DETAILED ACTION

This office action is in response to a communication dated 2/1/2010. Claims 1-5, 7-8, 10, 14-20, 22-25, 35-39, 42-46, 48, 52-58 are pending.

Response to Arguments

1. Applicant's arguments filed 2/1/2010 have been fully considered but they are not persuasive.

2. Applicant argues that the combination of Winston and Yoon does not disclose the insulation sliding relative to the instrument. Applicant also argues that "the movement/positionability of the sleeve of the currently-claimed device is impossible to achieve using either the barrel or the sleeves of Yoon's device with Winston's device". Examiner disagrees. The device only needs to be capable of performing the intended use. Winston in view of Yoon is capable of performing the function. Examiner also asserts that it would have been obvious to apply the device of Winston to the endoscopic sleeve and procedures as taught by Yoon. Providing the device of Winston with the sleeve of Yoon would allow the device to reach hard to reach places and provide insulation to protect the surrounding structures.

3. Applicant argues that "energy is not applied to the same element to achieve the same result". Examiner disagrees. Examiner contends that protecting the unintentional tissue damage should be consistent with both devices.

4. Applicant argues that Winston does not provide motivation to combine the invention with the sleeve of Yoon. Examiner disagrees. Winston discloses of the hot iron

having to reach temperatures up to 482°F (Column 2, Lines 44-61), so the "relatively cool temperature" in comparison to the "hot iron technique" is more than likely not completely safe for tissue contact. The device of Winston is intended to bond, weld, or fuse two plastic or metal sutures together (Column 6, Lines 25-34). If the device has that effect on sutures, it cannot have favorable effects to tissue. In addition, Yoon teaches of a similar device using ultrasonic energy with an insulation sleeve "for safety and protection". Given the teachings of Yoon, it would have been obvious to protect the tissue from ultrasonic energy with said sleeve.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-5, 7-8, 10, 14-20, 22-25, 35-39, 42-43, 44-46, 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Winston et al. ("Winston" 3,513,848)** in view of **Yoon (US 5,908,429).**

Winston discloses a device as shown in fig. 3A having two compression elements 57A and 46A. One is held rigidly to tube 70a and the other is slidably movable inside the outer tube. A spring 82a can bias the horn 57a either towards or away from anvil 46 (Column 11, Lines 24-47). A source of ultrasonic power 71a is attached to the device.

Winston discloses the invention as claimed with the exception of the specific compressive force. As Winston discloses that this force varies depending on the suture used, the prior art force applied by the spring being within the claimed range would have been expected to perform the intended function of the tightening of the suture as it would be sufficient to grip the suture and hold it steady during melting. Winston also fails to provide the insulating sleeve.

Yoon teaches of a surgical device comprising an instrument designed to transmit various forms of energy controllably positioned into an insulated sleeve **12** (Column 8, Lines 51-59). Additionally, **Yoon** teaches of a collar **22** that is capable of receiving an end portion of a suture by frictional engagement. Furthermore, **Yoon** teaches of the instrument being frictionally biased into a first position (Column 11, Lines 53-59).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to

one of ordinary skill in the art at the time of the invention. Given the teachings of **Yoon**, it would have been obvious to have provided **Winston** with such a sleeve, in order to protect the user and the patient from possible burns, while providing a sleeve through which the device could be inserted in order to suture internally.

The claimed limitation "the elongated insulation sleeve is further positionable to limit the application of energy from the energy source to the retainer received between the first and second compression elements" and the like is considered functional language. The device of **Winston** inherently has an on/off switch which also serves also a "safety switch". **Yoon** discusses the desirability of protecting the tissue from the energy emitted with the insulating sleeve. Therefore, if the user desires to protect the tissue from the ultrasonic energy, they are capable of preventing the on/off switch from being turned on in the presence of a certain sleeve configuration. The sleeve also inherently is capable of protecting a portion of the suture from the energy emitted.

8. **Claims 52-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Winston** in view of **Yoon** as applied to **claims 1, 24-25, 35, 43-44, 48** as above, and further in view of **Bates et al. ("Bates" US 6,348,056)**.

Winston in view of **Yoon** disclose all of the claimed limitations except for the proximal end of the elongated insulation sleeve including a channel for engaging a pin positioned on the second member, and wherein the channel and the pin cooperate to control a range of motion of the sleeve over the second member. However, **Bates**

teaches that it is commonly known in the art at the time of the invention to controllable move an instrument within a sleeve **12** by providing a pin **18** on the instrument and a groove **14** on the sleeve (FIG 11). All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Bates**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Winston** as modified by **Yoon** with a pin and groove. Doing so would provide an easy way to provide relative motion between the sheath and instrument.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773